UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

ZYLA LIFE SCIENCES, LLC,	§	
	§	
Plaintiff,	§	
	§	
VS.	§	CIVIL ACTION NO. 4:22-CV-04400
	§	
WELLS PHARMA OF HOUSTON, LLC,	§	
	§	
Defendant.	§	

ORDER

Before the Court are Plaintiff Zyla Life Sciences, LLC's First Amended Complaint (Doc. #9), Defendant Wells Pharma of Houston, LLC's Motion to Dismiss Plaintiff's First Amended Complaint and for Attorneys' Fees (the "Motion") (Doc. #20), Plaintiff's Response (Doc. #22), and Defendant's Reply (Doc. #25). Having considered the parties' arguments, submissions, and the applicable legal standards, the Court grants the Motion in part.

I. Background

Plaintiff Zyla Life Sciences, LLC is a Delaware corporation that markets and sells Indocin Suppositories, which contain the active pharmaceutical ingredient indomethacin. Doc. #9 ¶ 19. Plaintiff's Indocin Suppositories are the only Food and Drug Administration ("FDA") approved suppository products on the market that contain the active pharmaceutical ingredient indomethacin. *Id.* Indocin Suppositories serve to treat moderate to severe rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis, among other ailments. *Id.* ¶ 21. Plaintiff sells its product across the United States, including in California, Colorado, Florida, South Carolina, Tennessee, and Connecticut (collectively, the "Six States"). *Id.* ¶ 20.

Defendant Wells Pharma of Houston, LLC is a Texas limited liability company and registered compounding outsourcing facility under Section 503B of the Federal Food, Drug, and Cosmetic Act (the "FDCA").[1] Doc. #20 at 2; Doc. #9 ¶ 93; *see* 21 U.S.C. § 353b. "Drug compounding is the process by which a pharmacist combines or alters drug ingredients according to a doctor's prescription to create a medication to meet the unique needs of an individual . . . patient." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 387 (5th Cir. 2008). Defendant sells compounded indomethacin suppositories and ships its product to numerous states, including the Six States. Doc. #20 at 1; Doc. #9 ¶ 23. Defendant's indomethacin suppositories are not approved by the FDA. Doc. #9 ¶ 23.

On January 1, 2023, Plaintiff filed its First Amended Complaint against Defendant in this Court. Doc. #9. Plaintiff seeks to enjoin Defendant from manufacturing and selling its indomethacin suppositories in the Six States. *Id.* ¶ 1. Plaintiff does not allege any violation of Texas law. Rather, Plaintiff asserts that Defendant is in violation of: (1) California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200, *et seq.*; (2) the Colorado Consumer Protection Act, COLO. REV. STAT. § 6-1-105(z), and Colorado Common Law of Unfair

[1] While Plaintiff insinuates in its First Amended Complaint that Defendant is in the business of compounding, it fails to mention that Defendant is a registered compounding facility under the FDCA. *See* Doc. #9 ¶¶ 29, 93. However, in evaluating a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss, the Court may take judicial notice of some facts, including "matters of public record" such as "publicly available documents and transcripts produced by the FDA." *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011); *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017–18 (5th Cir. 1996). "Wells Pharma of Houston, LLC" is listed by the FDA as a registered compounding outsourcing facility under Section 503B of the FDCA. U.S. FOOD AND DRUG ADMINISTRATION, *Registered Outsourcing Facilities* (last updated Aug. 25, 2023), https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities. Thus, the Court takes judicial notice of this fact. However, this does not mean, as Plaintiff suggests, that the Court also takes notice that Defendant complies, or does not comply, with the FDCA's requirements for compounding facilities—the Court merely takes note that Defendant is indeed a registered compounding facility. *See* Doc. #22 at 6–7.

Competition; (3) Florida's Deceptive and Unfair Trade Practices Act, FLA. STAT. ANN. § 501.201, *et seq.*; (4) the Tennessee Consumer Protection Act, TENN. CODE ANN. 47-18-104(b)(43)(C); (5) the South Carolina Unfair Trade Practices Act, S.C. CODE ANN. § 39-5-20; and (6) the Connecticut Unfair Trade Practices Act, CONN. GEN. STAT. § 42-110b. *Id.* ¶¶ 49–95. The basis of Plaintiff's claims is that Defendant sells "unapproved" pharmaceutical drugs in the Six States, all of which have statutes requiring premarket FDA approval. Four of the states that Plaintiff brings its claims under—Colorado, Florida, Tennessee, and Connecticut—require premarket approval of pharmaceutical drugs by the FDA in order to be sold in the state.[2] The other two states—California and South Carolina—require drugs to be approved either under federal law or by their respective state health departments.[3]

Because the Six States require premarket approval, Plaintiff claims that Defendant is in violation of each state's respective unfair competition laws. Plaintiff further asserts that Defendant's unlawful selling of indomethacin suppositories in these states has (1) jeopardized public health and (2) harmed Plaintiff because "[s]ales made by Defendant in each of these states

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[2] In Colorado, it is unlawful to sell pharmaceutical drugs that are "not authorized to move in interstate commerce *under appropriate federal law*." COLO. REV. STAT. § 12-280-131 (emphasis added). Florida prohibits the selling and marketing of new drugs unless "an approved application has become effective *under s. 505 of the federal act* or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services." FLA. STAT. ANN. § 499.023 (emphasis added). Tennessee prohibits the sale of new drugs "unless an application with respect to the drug has *become effective under § 505 of the federal act*." TENN. CODE ANN. § 53-1-110 (emphasis added). And Connecticut prohibits selling new drugs unless "an application with respect thereto has been approved *under Section 355 of the federal act*." CONN. GEN. STAT. § 21a-110 (emphasis added).

[3] In California, "new drugs" may not be sold unless an "application has been approved for it . . . *under Section 505 of the federal act* (21 U.S.C. Sec. 355)" or "the [State Department of Health Services] has approved" it. CAL. HEALTH & SAFETY CODE § 111550(a)–(b) (emphasis added). In South Carolina, it is unlawful to sell a new drug "unless an application filed [with the Director of the South Carolina Department of Health and Environmental Control] is effective with respect to such drug, or an application with respect thereto has been approved . . . *under § 505 of the Federal act*." S.C. CODE ANN. § 39-23-70(a) (emphasis added).

would have been made by Plaintiff, but for Defendant's unlawful and unfair competition." *Id.* ¶ 47. In short, Plaintiff believes it was harmed because it is the only supplier of FDA-approved indomethacin suppositories, and Defendant is the only "known" seller of the non-approved version of the drug. *Id.* ¶ 46.

Defendant now moves to dismiss all of Plaintiff's claims and seeks attorneys' fees. Doc. #20. Defendant's chief argument is that all of Plaintiff's state law claims are preempted by federal law. Doc. #20 at 7–13. Pursuant to Section 505 of the FDCA, most prescription drugs require premarket approval by the FDA in order to be sold. 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."). However, the FDCA creates an exception to this premarket approval requirement for qualifying compounding outsourcing facilities. *See* 21 U.S.C. § 353b ("[Section 355(a)] shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility."). In addition, 21 U.S.C. 337(a) bars private enforcement of the FDCA. As such, Defendant argues that because the FDCA explicitly authorizes the sale of compounded drugs without premarket approval, Plaintiff's claims that the laws of the Six States require Defendant—a compounding facility—to seek FDA approval are preempted and must be dismissed. Doc. #20 at 7–8. Defendant further asserts that Plaintiff's state law claims are a "thinly veiled attempt to usurp the exclusive enforcement power of the FDA." *Id.* at 1. In the event of dismissal, Plaintiff seeks leave to amend its First Amended Complaint. Doc. #22 at 18.

II. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss under the Federal Rules of Civil Procedure, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This plausibility standard is satisfied "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* In its analysis of a Rule 12(b)(6) motion to dismiss, a court may consider the complaint, any documents attached to the complaint, and matters of which it takes judicial notice. *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017–18 (5th Cir. 1996). In evaluating the complaint, the court takes "the well-pleaded factual allegations in the complaint as true" but does "not credit conclusory allegations or allegations that merely restate the legal elements of a claim." *Chhim v. Univ. of Tex. at Austin*, 836 F.3d 467, 469 (5th Cir. 2016).

III. Analysis

a. Federal Preemption at the Rule 12(b)(6) Motion to Dismiss Stage

As a threshold matter, Plaintiff argues that Defendant prematurely raises a federal preemption defense at the motion to dismiss stage. Doc. #22 at 5–6. "Federal preemption is an affirmative defense that a defendant must plead and prove." *Fisher v. Halliburton*, 667 F.3d 602, 609 (5th Cir. 2012). However, when "the complaint itself establishes the applicability of a federal-preemption defense[,] . . . the issue may properly be the subject of a Rule 12(b)(6) motion." *Id.* Thus, a Rule 12(b)(6) dismissal may be warranted "when a successful affirmative defense appears on the face of the pleadings." *Kansa Reinsurance Co. v. Cong. Mortg. Corp. of Tex.*, 20 F.3d

1362, 1366 (5th Cir. 1994). Indeed, this Court has granted 12(b)(6) motions based on federal preemption stemming from the FDCA. *See, e.g.*, *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 710–11 (S.D. Tex. 2014) (dismissing state laws claims brought by the plaintiff against a medical device manufacturer based on federal preemption). Here, the Court finds that Defendant's federal preemption defense is not premature because Plaintiff's First Amended Complaint "establishes the applicability of a federal-preemption defense." *See Fisher*, 667 F.3d at 609.

b. Federal Preemption of Plaintiff's State Law Claims

Defendant moves to dismiss Plaintiff's First Amended Complaint in its entirety, arguing that each claim is preempted by federal law. Doc. #20 at 7. Preemption doctrine arises under the Constitution's Supremacy Clause, which "invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824)). Federal law may expressly or impliedly preempt state law. Express preemption occurs when Congress includes "explicit preemptive language" in the statute. *Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203–04 (1983). Implied preemption exists in "instances where the challenged state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Here, Defendant relies on implied preemption. In analyzing whether a state law claim is preempted under the FDCA, "an independent state-law duty may form the basis of a tort claim for which violations of the FDCA may be presented as evidence of breach, assuming that the state-law claims do not (a) 'add to' federal requirements or (b) impinge on the FDA's sole authority" over enforcement. *Spano as next friend of C.S. v. Whole Foods, Inc.*, 65 F.4th 260, 264 (5th Cir.

2023). In other words, the FDCA does not preempt state-law claims that "parallel" the federal requirements, so long as the state laws do not threaten or interfere with the federal requirements. *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006).

Plaintiff claims that Defendant, an FDA-registered compounding facility, is violating the Six States' unfair competition laws because it failed to obtain premarket approval prior to selling pharmaceutical drugs. The Fifth Circuit has not directly addressed whether the FDCA preempts state law claims based on alleged noncompliance by FDA-regulated compounding facilities.[4] However, in *Spano*, the Fifth Circuit analyzed implied preemption in the context of the FDCA's food-labeling requirements. *Spano*, 65 F.4th at 262–63. The Fifth Circuit noted that the FDCA contains no private right of action. *Id.* at 262 (citing 21 U.S.C. § 337(a)). Yet, the court held that "an independent state-law duty may form the basis of a tort claim for which violations of the FDCA may be presented as evidence" as long as the "state-law claims do not (a) 'add to' federal requirements or (b) impinge on the FDA's sole authority over food-labeling requirements." *Id.* at 264.

The Fifth Circuit in *Spano* found that the plaintiffs' claims were not preempted. First, the court reasoned that the plaintiffs did not seek to enforce the FDA's food-labeling requirements through its state law claims because the state claims did not impose requirements "*beyond* those

[4] The Ninth Circuit, however, has addressed this issue in a case with facts similar to those presented here. *See Nexus Pharm., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1042 (9th Cir. 2022). In *Nexus*, the Ninth Circuit affirmed a Rule 12(b)(6) dismissal of state law unfair competition claims against an outsourcing facility. *Id.* at 1041. There, as here, the plaintiff drug manufacturer sold an FDA-approved drug and sought to enjoin the defendant compound pharmacy from selling a non-approved compounded variation of that drug. *Id.* 1042–43. Based on the FDCA's exclusive enforcement provision, 12 U.S.C. § 337(a), the Ninth Circuit held that the plaintiff's state-law claims were preempted. The court reasoned that allowing an action alleging FDA violations to proceed when the FDA has not made such a determination would essentially permit the plaintiff to assume enforcement power that the FDCA does not allow. *Id.* at 1049.

imposed by the FDA." *Id.* (emphasis added). Second, the plaintiffs' claims did not appear to impinge on the FDA's authority over food labeling because their claims did not "depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue." *Id.* (quoting *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011)). The Fifth Circuit therefore reversed the district court's 12(b)(6) dismissal and held the plaintiffs' claims were not preempted. *Id.* at 265.

Plaintiff alleges that Defendant's sale of non-approved indomethacin suppositories violates the Six States' unfair competition laws. While most prescription drugs require premarket approval, the FDCA excepts qualifying compounding outsourcing facilities from this requirement. *See* 21 U.S.C. § 353b. As such, Plaintiff's assertion that Defendant must obtain premarket approval under the laws of the Six States adds to the federal requirements under the FDCA—which does not require compounding facilities to acquire premarket approval. *See Spano*, 65 F.4th at 264. Plaintiff thus seeks to enforce premarket approval requirements for registered compounding facilities "beyond" those imposed by the FDA. *See id.* Further, Plaintiff's state law claims "impinge on the FDA's sole authority" over enforcement of the FDCA's drug approval requirements. *See id.* Plaintiff's claims "depend on speculation" that the FDA would have taken regulatory action in response to Defendant's sale of compounded indomethacin suppositories, as Plaintiff does not allege that Defendant violated the FDCA but asserts state law claims that hinge on FDCA compliance. *See id.* Indeed, Plaintiff fails to plead any facts to support the assertion that Defendant is noncompliant with the compounding provisions of the FDCA, while relying on state laws that require compliance with the FDCA.

Plaintiff cites various Fifth Circuit cases in which the court found that certain state law claims that paralleled federal requirements were not preempted by the FDCA. *See* Doc. #22 at 10

(citing *Gomez*, 442 F.3d 919; *Hughes*, 631 F.3d 762; *Bass v. Stryker Corp.*, 669 F.3d 501 (5th Cir. 2012)). All of these cases are distinguishable. Each case emphasizes that the state law at issue did not create a requirement that was "'different from or in addition to' a federal requirement." *Hughes*, 631 F.3d at 768; *Gomez*, 442 F.3d at 929; *Bass*, 669 F.3d at 507. As discussed, the state law claims raised by Plaintiff seek to create a requirement "in addition to" the FDCA's requirements—that premarket approval is required for drugs regardless of whether they are produced by compounding facilities. *Supra* pp. 7–8. Because federal law does not require such approval, Plaintiff's claims are preempted, and Defendant's Motion is granted.

c. Defendant's Request for Attorneys' Fees

Defendant also moves for attorneys' fees. Doc. #20 at 18. However, Defendant solely relies on Florida law and Eleventh Circuit cases to support its request, neither of which are binding upon this Court. As such, Defendant's request for attorneys' fees is denied.

d. Plaintiff's Request for Leave to Amend its Complaint

Plaintiff requests leave to amend its First Amended Complaint to allege that Defendant does not comply with the various compounding provisions of the FDCA. Doc. #22 at 6, 19. Federal Rule of Civil Procedure 15(a) states that "leave shall be freely given when justice so requires." However, "[a] district court acts within its discretion when dismissing a motion to amend that is frivolous or futile." *Martin's Herend Imports, Inc. v. Diamond & Gem Trading U.S. of Am. Co.*, 195 F.3d 765, 771 (5th Cir. 1999); *see also Ayers v. Johnson*, 247 F. App'x 534, 535 (5th Cir. 2007). Here, the Court finds that amendment would be futile. Even if Plaintiff amended its complaint to address Defendant's compliance with the FDCA's compounding requirements, Plaintiff's state law claims would still be preempted by the FDCA's exclusive enforcement provision. *Nexus Pharm., Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040, 1042

(9th Cir. 2022) (holding the plaintiff's state law unfair competition claims were preempted where the basis of the claims was the defendant outsourcing facility's alleged noncompliance with the FDCA compounding requirements); 12 U.S.C. § 337(a). Thus, Plaintiff's claims are preempted and its request for leave to amend is denied.

IV. Conclusion

In conclusion, the Court finds that all of Plaintiff's claims are preempted by federal law. Each of Plaintiff's claims are premised on the theory that the Six States' laws require compounding facilities to obtain premarket approval, which is not a requirement under the FDCA. Thus, the Six States' laws "add to" the federal requirements and are therefore preempted. As such, Defendant's Motion to Dismiss (Doc. #20) is GRANTED IN PART. In addition, Defendant's request for attorneys' fees is DENIED because Defendant relies on nonbinding law. Plaintiff's request for leave to amend its First Amended Complaint is DENIED because amendment would be futile.

It is so ORDERED.

SEP 27 2023
Date

The Honorable Alfred H. Bennett
United States District Judge